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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
BANSAL,G	
ART UNIT	**PAPER NUMBER**
1642	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/522716	Cohen
Examiner	**Group Art Unit**
Geetha Bansal	1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 3-10-00.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☒ Claim(s) 8, 4, 16, 26, 29-46 is/are pending in the application.

Of the above claim(s) 3, 4, 16, 29-38 is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s)_____ is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10 Sheets ☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other_____

Office Acti n Summary

DETAILED ACTION

1. Applicant's election with traverse of Group III (claims 26, 39-46) in Paper No.5 is acknowledged. The traversal is on the ground(s) that the methods of Group II and Group III are both effected by administering semi-allogeneic cells or hybrid cells and that therefore they are related. Further Applicant argues that the classification system is arbitrary and is an aid in finding and searching for patents. This is not found persuasive because the restriction groups were made based on the distinct differences between the inventions and the independent nature of each of those inventions in that none of them needs or is dependent upon the other for standing alone as a patentable invention. The method of eliciting an immune response is quite independent of producing a therapeutic effect in that one can induce an immune response to several irrelevant antigens, whereas a protective immunity is generated by very specific epitopes on specific antigens. Each of the groups are supportive of different patents that are distinct and independent as explained earlier.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 29, 36-49 are being examined.

3. The elected claims are drawn to a method of preventing or treating cancer by administering to an animal an effective composition of semi-allogeneic immunogenic cells which cell comprises an antigen presenting cell (APC) expressing at least one class I or class II MHC determinant that is syngeneic to said animal and at least one class I or class II MHC determinant that is allogeneic to the animal and wherein said APC is transfected with and expresses DNA from the tumor cells of said animal. Further claims are drawn to limitations where the type of tumor is specified, the type of APC is specified and the further inclusion of cytokines is specified. The semi-allogeneic cell is also claimed as a fused cell obtained by fusing together tumor cells and APCs.

Claim Rejections - 35 U.S.C. § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 26, 39-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As elaborated in paragraph #2, the claims are drawn to specific uses. The specification discloses making and using a fibroblast cell line of the H2-K^k MHC class I determinant transfected with gene for H2-K^d MHC class I determinant, as well as DNA encoding IL-2 and genomic DNA from B16 (H2-$K^{k)}$ tumor cells. The specification discloses the prevention of tumor growth as well as inhibition in growth of established tumors by administering the semiallogeneic transfected cell of the instant application.

A. With respect to prevention of cancer, there is no teaching or guidance provided in the specification as to how prevention of cancer in an animal species such as a human, can be achieved in that there is no method taught as to how one of skill in the art would be able to ascertain that the subject was prophylaxed against the tumor successfully or that subject was never going to get the tumor at all. An effective therapeutic protocol for the treatment or prevention of the formation of a tumor is subject to a number of factors which enter the picture beyond simply the specific binding of an antibody or a T cell line to the tumor cell line derived antigen. Demonstrating tumor antigen specificity in vitro cannot alone support the predictability of the method for prevention of or treating said tumor growth through administration of either a tumor cell antigen specific antibody or T cell line expressing the appropriate idiotope. The establishment and growth of a tumor is subject to variables beyond antigen specificity. The ability

of a host to suppress and thereby prevent the tumor from establishing itself will vary depending upon factors such as the condition of the host, the type of tumor (rapidly proliferating or slowly proliferating) and the tumor burden. See Evans et al. 1999 who indicate that the goal of most vaccines is therapeutic efficacy- i.e. not sought to be developed to prevent the occurrence of cancer much as one would do with respect to infectious diseases (page 299, column 1 beginning of second section). Evans et al discuss various scenarios for combating cancer and it appears clear to one of skill in the art that cancer prevention is an unpredictable art and really varies from tumor to tumor and the knowledge of the availability of protective tumor antigens. Evans et al conclude that (page 303, last column) - that the notion that cancer vaccines will replace standard therapeutic strategies in malignant disease still belongs to the realm of fiction.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 43 is rejected under 35 U.S.C. 102(b) as being anticipated by Payelle et al (1981).

The claims are drawn to preventing or treating a tumour by administering to an animal a semi-allogeneic hybrid cell wherein the hybrid cell is formed by fusing a tumor cell to a fibroblast and wherein the hybrid cell expresses at least one class I or class II MHC determinant to that is syngeneic to said animal and at least one class I or class II MHC determinant that is allogeneic to the animal. Payelle et al teaches the induction of protective T cells against a fibrosarcoma tumor(MCB6-1) by administering a hybrid cell made from fusing the fibrosarcoma(MCB6-1) to a fibroblast cell (A9). The hybrid cell is expressed both MHC class I antigens. It is noted that this reference anticipates the exemplification disclosed in the specification.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 39-40, 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payelle et al (1981) in view of Kundig et al (1985).

The claims are drawn to preventing or treating a tumour by administering to an animal a semi-allogeneic hybrid cell wherein the hybrid cell is formed by fusing a tumor cell to an APC and wherein the hybrid cell expresses at least one class I or class II MHC determinant to that is syngeneic to said animal and at least one class I or class II MHC determinant that is allogeneic to the animal. Payelle et al teaches the induction of protective T cells against a fibrosarcoma tumor(MCB6-1) by administering a hybrid cell made from fusing the fibrosarcoma(MCB6-1) to a fibroblast cell (A9). The hybrid cell is expressed both MHC class I antigens. It is noted that this reference anticipates the exemplification disclosed in the specification. Payelle et al do not specifically indicate the fusion to be performed with any APC. However, from the teachings of Kundig et al it is clear that fibroblasts are also antigen presenting cells. It is also clear to one of ordinary skill in the art that the conventional APCs (macrophages, as well as B cells and dendritic cells) would function similarly in the APC functions. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to fuse a tumor cell with an antigen presenting cell to produce a hybrid cell which would have the tumor cell antigen as well as the antigen presentation in the context of the MHC molecules to the T cells in order to evoke a therapeutic efficacy against the tumor cell. One of ordinary skill in the art would be motivated by the success demonstrated by Payelle et al that teaches a method of preventing or treating a tumor by administering a hybrid cell as claimed. To the extent that the specification exemplifies and

rationalizes the methods of the claimed invention, the combination of the prior art references renders the invention obvious to one of ordinary skill in the art.

10. No claim is allowable.

11. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308- 3995.

10. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Sept. ~~July~~ 12, 2001

GEETHA P. BANSAL
PRIMARY EXAMINER